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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,049	12/01/2003	Erming Xia	P03373	2954
23702 7590 03/12/2007 Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701			EXAMINER CHORBAJI, MONZER R	
			ART UNIT	PAPER NUMBER
			1744	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/725,049

Applicant(s)

XIA ET AL.

Examiner

MONZER R. CHORBAJI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6 and 9-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6 and 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

This final action is in response to the RCE/Amendment received on 01/22/2007

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 5-6 and 9-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellis et al (U.S.P.N. 4,436,730).

Regarding claim 1, Ellis discloses an aqueous ophthalmic solution (col.1, lines 61-67 and col.5, lines 9-15) that includes quarternized ammonium cationic polysaccharides (col.10, lines 26-41 and examples VI-VII) in an amount effective for solution preservation (example VI and col.2, lines 54-62). As to the limitation, "consisting of", Ellis teaches that the use of preserving agent is optional and is not basic and required part of the composition (col.7, lines 44-49) that if desired, it can be included in the composition. One of ordinary skill in the art would recognize that in certain embodiments the composition would include an aqueous ophthalmic solution along with quarternized ammonium cationic polysaccharides as the only source of preservatives (as the instant amended claim recites) while in other embodiments additional preservatives are added to the quarternized ammonium cationic polysaccharides.

Regarding claims 3 and 6, Ellis employs variations of polyquaternium 10 (example IV).

Regarding claims 5 and 13-15, Ellis discloses a method where cationic polysaccharides (example IV) is combined in amount effective (examples V-VII) for solution preservation (col.2, lines 54-62) where surfaces of contact lenses (i.e., medical items) are treated over a time interval so that microbial burden (col.2, lines 59-62 and col.7, lines 59-61) on contact lenses is eliminated.

Regarding claims 9-12, Ellis teaches the following: the use of a buffer (col.7, lines 57-59), the use of tonicity agents (Example V), the use of surfactants (col.7, lines 56-57) and the use of viscosity agents (col.7, lines 49-50).

Response to Arguments

3. Applicant's arguments filed on 01/22/2007 have been fully considered but they are not persuasive.

On page 4 of the Remarks section, applicant argues that, "Ellis did not recognize that the quarternized ammonium cationic polysaccharides could be used in an ophthalmic composition to preserve the ophthalmic compositions where such compositions are suitable to the eyes". Ellis's composition is suitable to the eyes, for example, see col.7, lines 64-67 or see bottom of column 15 to top of column 16. With respect to recognizing that the polysaccharides act as ophthalmic solution preservatives, see MPEP 2112, II and MPEP 2112.01.

On page 4 of the Remarks section, applicant argues that, "Accordingly, in each instance Ellis used an additional preservative in an amount effective to, at a minimum,

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preserve the solution or disinfect the solution.” Ellis teaches that the use of preserving agent is optional and not basic and required part of the composition (col.2, lines 59-62 and col.7, lines 44-49) that if desired, it can be included in the composition. In some of the illustrated embodiments, Ellis has optionally included additional preserving agents so that synergistic effects of such agents result in increasing the strength of preservation. However, the fact that Ellis illustrates combining preservative agents with quarternized ammonium cationic polysaccharides does not negate his teaching in col.7, lines 44-49 that in some embodiments the composition will only include quarternized ammonium cationic polysaccharides as the source of preserving agent.

On bottom of page 4 of the Remarks section, applicant argues that the use of the transitional phrase “consisting of” means that the source of preservative agents is only quarternized ammonium cationic polysaccharides. Again, Ellis teaches that the use of preserving agent is optional and not basic and required part of the composition (col.2, lines 59-62 and col.7, lines 44-49) that if desired, it can be included in the composition. Therefore, in some embodiments the composition will only include quarternized ammonium cationic polysaccharides as the source of preserving agent and this teaching meets the transitional phrase “consisting of”.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next office action if they had been

entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

5. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MONZER R. CHORBAJI** whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 9:00-5:30.

7. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **GLADYS J. CORCORAN** can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MRC


GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER